

**UNITED STATES AIR FORCE
ARMSTRONG LABORATORY**

**TESTING AND EVALUATION OF THE
BCI 3303 PULSE OXIMETER**

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May 1998

19980721 065

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DTIC QUALITY INSPECTED 2

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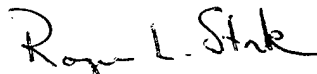
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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE MAY 98	3. REPORT TYPE AND DATES COVERED Final, June 1997		
4. TITLE AND SUBTITLE Testing and Evaluation of the BCI 3303 Pulse Oximeter		5. FUNDING NUMBERS PE: 62202F PR: 7184 TA: 56 WU: 01		
6. AUTHOR(S) Douglas S. Townsend				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Systems Research Branch 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104		8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Air Force Research Laboratory (AFMC) Human Effectiveness Directorate Flight Stress Protection Division 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104		10. SPONSORING/MONITORING AGENCY REPORT NUMBER AL-CF-BR-TR-1998-0015		
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION AVAILABILITY STATEMENT Approved for public release; distribution unlimited.		12b. DISTRIBUTION CODE		
13. ABSTRACT (Maximum 200 words) The BCI International, Inc., Model 3303, Pulseo Oximeter is a portable pulse oximeter that measures SpO2 and pulse through the use of either a disposable probe or a reusable finger probe. The unit operates on 115 VAC/60 Hz and an internal rechargeable battery pack				
14. SUBJECT TERMS BCI aircraft medical equipment 3303 approved aeromedical airworthy Pulse Oximeter			15. NUMBER OF PAGES 21	
16. PRICE CODE				
17. SECURITY CLASSIFICATION OF REPORT UNCLASSIFIED	18. SECURITY CLASSIFICATION OF THIS PAGE UNCLASSIFIED	19. SECURITY CLASSIFICATION OF ABSTRACT UNCLASSIFIED	20. LIMITATION OF ABSTRACT UL	

TABLE OF CONTENTS

BACKGROUND	1
DESCRIPTION	1
PROCEDURES	3
INITIAL INSPECTION AND TEST PREPARATION	4
TEST SETUP	4
PERFORMANCE CHECK	5
VIBRATION	5
ELECTROMAGNETIC COMPATIBILITY	7
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS	8
HYPOBARIC CONDITIONS	9
AIRBORNE PERFORMANCE	9
EVALUATION RESULTS	10
INITIAL INSPECTION	10
VIBRATION	10
ELECTROMAGNETIC COMPATIBILITY	10
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS	11
HYPOBARIC CONDITIONS	11
AIRBORNE PERFORMANCE	11
SUMMARY	12
REFERENCES	13
APPENDIX	14

LIST OF FIGURES

Figure 1. BCI 3303 System	2
Figure 2. Test Setup	4
Figure 3. Mil-STD 810E, Category 10, Figures 514.4-16 and 514.4-17	6

ACKNOWLEDGMENTS

I would like to thank those who helped and provided advice during the evaluation of the BCI 3303 System. I would particularly like to thank:

Lt. Col. Jacqueline Hale
Mr. Edward W. Hade
MSgt. Butch Blake
TSgt. Allen Jones

TESTING AND EVALUATION OF THE BCI 3303 PULSE OXIMETER

BACKGROUND

BCI International requested that Armstrong Lab evaluate the BCI 3303 system for use on board USAF aeromedical evacuation aircraft. Components of the 3303 system include the 3303 pulse oximeter, serial number 160205102, a 24VDC power supply (catalog number 8210), a reusable finger probe (serial number 260214486), and the protective cover. The 3303 pulse oximeter, the model 8210 power supply and the reusable finger probe were tested for airworthiness. Throughout this report "3303" refers to the 3303 pulse oximeter and "3303 system" refers to 3303 pulse oximeter, the model 8210 power supply, and the reusable finger probe.

DESCRIPTION

The 3303 is a portable pulse oximeter that measures SpO_2 and pulse through the use of either a disposable probe or a reusable finger probe. SpO_2 is defined as the arterial O_2 saturation measured by a pulse Doppler technique. The disposable probe comes in a variety of sizes to fit adults to neonates and may be used at various points on the patient's body. The rechargeable internal battery will last 12 hour nominal use without recharging. A 115VAC/60 Hz power supply is used to either recharge the battery or operate the unit continuously while the battery is trickle charged. Any time the 115 VAC/60Hz power supply is connected, the battery is maintained even if the 3303 is turned off.

The 3303 has SpO_2 and pulse rate numeric LED displays, an eight-segment LED pulse strength bar graph, probe light, battery light, and alarm-silenced light. There is a power light that indicates the 115 VAC/60Hz power supply is attached. The charging light is yellow when the battery is fast charging and off when the battery is fully charged.

The 3303 has controls for on, off/standby, volume alarm, volume pulse, I.D. clear, volume up and down, alarm silence, and alarm select. The operator can set the alarm and pulse volume to individual preference. The "I.D. clear" is used to reference multiple patients each time the button is pressed, or the stored patient data can be erased and the patient counter reset.

The 3303 has three modes of operation: Clinician, Home-use, and Sleep Study. The Clinician mode is for use by health care professionals, the Home-use mode permits the home-use caregiver to monitor a patient at home and also record the data

for later analysis, and the Sleep Study mode allows the health care professional to record sleep study data for later analysis on a PC computer.

General Specifications Of The BCI 3303 Pulse Oximeter

Size	84 mm (3.3 in)	184 mm (7.25 in)	47 mm (1.85 in)
Weight	19 ounces (539 grams)		
SpO2 range	0% - 100%		
Pulse Rate	30 - 254 BPM		



Figure 1. BCI 3303 System

PROCEDURES

Test methods and performance criteria were derived from military standards (1-3 & 8-9), nationally recognized performance guidelines (4 & 7), and manufacturer's literature (5). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (6). A test setup and performance check were developed specifically for this product to verify proper functioning of the equipment under various testing conditions. Unless otherwise noted all testing is conducted and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX.

The device was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)
4. Thermal/Humidity, Environmental Conditions, Encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity Operation
 - d. Hot Temperature Storage
 - e. Cold Temperature Storage
5. Hypobaric Conditions
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient Pressure
6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The BCI 3303 system was inspected for quality of workmanship, production techniques, and possible damage incurred during shipment.
- b. The BCI 3303 system was checked to ensure it met basic human factors design requirements as outlined in Mil STD 1472 (3).
- c. A test setup and performance check were developed to evaluate the BCI 3303 systems operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The 3303 was connected to the BCI simulator model number 1606 serial number 430038041. The displayed values should be 97-99% for SpO₂ and 79-81 beats per minute for pulse. The normal displayed values were 98% for SpO₂ and 79 BPM for pulse.

BCI 3303, Test Set-Up

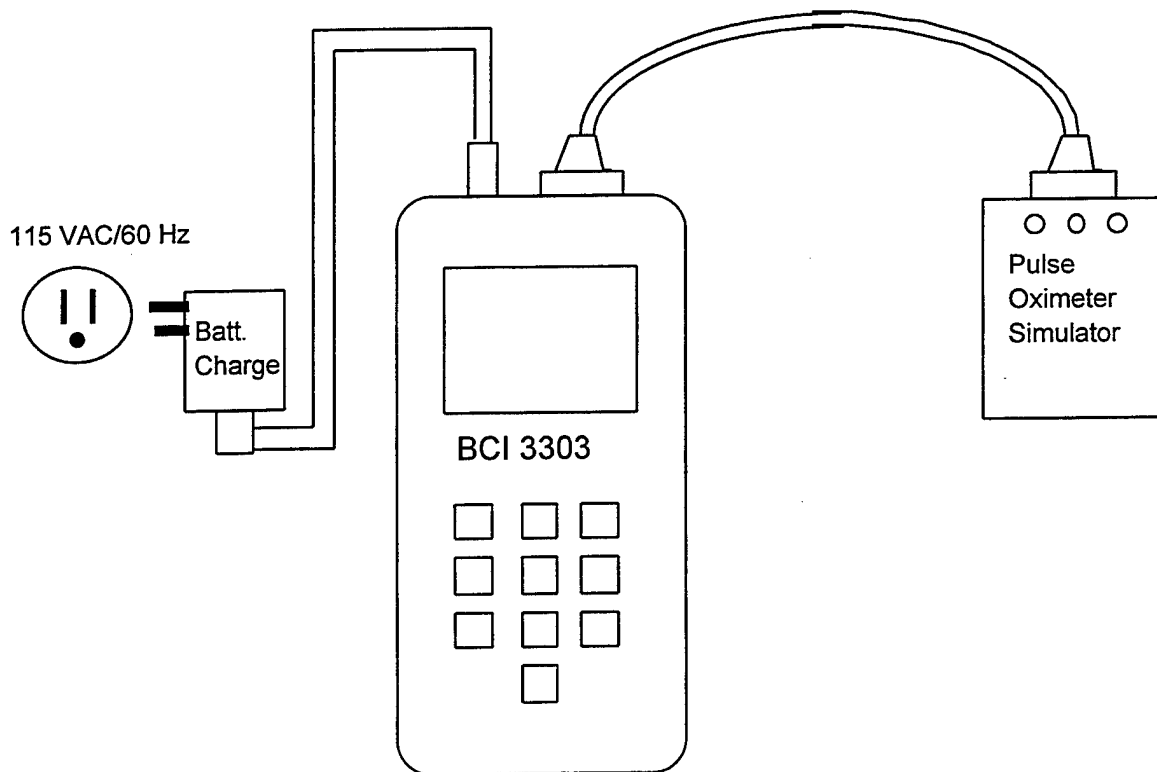


Figure 2. Test Setup

PERFORMANCE CHECK

The 3303 was connected to the power supply and monitored to determine if the charge and power light were functioning. The displayed values of the 3303 while connected to the BCI simulator were recorded. The probe was placed on a human finger to determine if the displayed values would change appropriately.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (2). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of the BCI 3303 systems three axes - X, Y, and Z, with the BCI 3303 system components mounted on the NATO litter segment on the vibration table as they would be in the aircraft. The BCI 3303 was subjected to vibration curves that are derived from Mil STD 810E, /Category 10, Figures 514.4-16 and 514.4-17 (Figure 3).

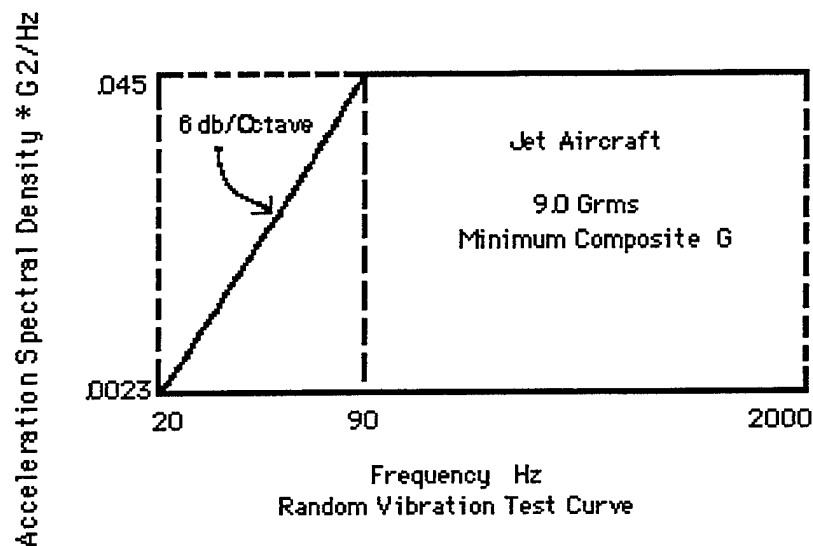
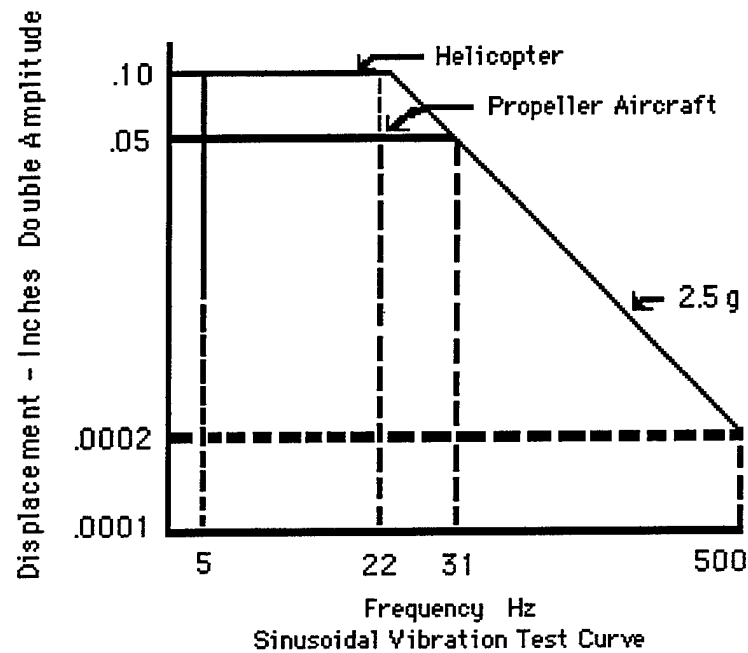


Figure 3. Mil-STD 810E, Category 10, Figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor in assessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Medical devices may also be susceptible to electromagnetic interference (EMI) fields generated by the aircraft equipment or other medical devices.

The BCI 3303 system was evaluated for compliance with Mil STD 461D (1). WL/AASW Wright-Patterson AFB performed the evaluation in their electromagnetic compatibility facility. ASC/ENAI, Wright-Patterson AFB, evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the system under test during its operation.

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions reflected back down the power supply lines by the system under test.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": for Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test evaluate the resistance of the system under test to set levels of EMI generated by both internal and external aircraft antennas.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determine the ability of the system under test to withstand "ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout a narrower portion of the frequency

band, from 10 kHz to 200 MHz. This test determine whether "simulated currents which were developed on platform cabling from electromagnetic fields generated by antenna transmission both on and off the platform" would affect the system under test.

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test evaluated the resistance of the system under test to the "fast rise and fall time transients that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

The 3303 was tested both on battery and line power. The alarms were triggered when possible but, due to testing constraints, the alarms could not be on continuously.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extremes of temperature and humidity testing are critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance" (2). Extreme environmental conditions can have numerous detrimental effects on medical equipment including changes in material characteristics and material dimensions, possible overheating, changes in electronic component characteristics, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory environmental chambers. The 3303 system was placed in the chamber. The power supply was plugged into an extension cord that was run out of the chamber through a port in the chamber wall, sealed with a precut sponge plug. The reusable finger probe was placed in the environmental chamber and the plug run outside of the chamber through another port sealed like the AC power cord. A 5-ft extension cord was connected to the 3303 and run out of the chamber through the same port as the finger probe. For most of the test the BCI simulator was connected to the 3303. At random times during the test the reusable finger probe was connected to the 3303 and placed on a human finger. This protocol insured that the values displayed were actually changing. For operational tests, the 3303 system was monitored continuously and a performance check was performed every fifteen minutes. For storage tests, the 3303 system was placed in the chamber and remained inoperative throughout the test. The following describes the conditions of the environmental tests performed.

- a. Humidity: 94 +/- 4% RH, 85 +/- 3.6°F (29.5 +/- 2°C) for 4 hours
- b. Hot Temp Operation: 120 +/- 3.6°F (49 +/- 2°C) for 2 hours

- c. Cold Temp Operation: 32 +/- 7.2°F (0 +/- 2°C) for 2 hours
- d. Hot Temp Storage: 140 +/- 3.6°F (60 +/- 2°C) for 6 hours
- e. Cold Temp Storage: -40 +/- 3.6°F (-40 +/- 2°C) for 6 hours

HYPOBARIC CONDITIONS

Testing was conducted in the Armstrong Laboratory research chambers.

a. Cabin pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000 - 10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the 3303 system while ascending from ground level to 10,000 ft (maintaining altitude for one hour) and then descending back to ground, at rates of 5,000 ft/min, while stopping at 2,000 ft increments for performance checks.

b. Rapid Decompression Testing: Rapid decompression is caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The 3303 system was operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent altitude of 8,000 ft (2,430 meters). Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground level at a rate of 10,000 - 12,000 ft/min. The test was repeated two more times with decompression periods of seven and one second, respectively. The 3303 system was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Connections for the simulator and the power supply for the 3303 were run through putty-sealed access ports in the chamber walls.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual

environment, Aeromedical Research ensures that all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation of this medical equipment support device is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical flight nurse and aeromedical research technicians onboard both a C-9 and C-130 aeromedical evacuation mission. The 3303 was carried by the Aeromedical Research technician and the reusable finger probe was placed on the technician's finger. Human factors characteristics, securing methods, and equipment setup times and location were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. The unit has an all plastic case; therefore, no electrical safety tests were done.

VIBRATION

During vibration the reusable finger probe connector repeatedly came loose at the probe input port on the 3303. The power supply connector at the 3303 also came loose repeatedly during testing. After using duct tape to tape the connectors to the 3303, no further vibration related problems were noted.

ELECTROMAGNETIC COMPATIBILITY

While doing EMI testing at Wright-Patterson AFB, the 3303 system emitted EMI levels above those allowed in the Mil-STD for RE-102 and CS-114. ASC/ENAI issued a letter stating that even though the RE-102 emissions of the 3303 system exceeded the stated limits the unit could still be used on any U.S. Air Force aircraft. The Aeromedical Research group issued a letter dated 8 Oct 96 stating that even though the 3303 system failed the CS-114 test the 3303 system could be used on U.S. Air Force aircraft for patient monitoring but only on battery power. The power supply could be used to charge the battery while on the aircraft, but not when monitoring a patient.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The 3303 system operated satisfactorily during all five phases of thermal/humidity testing.

HYPOBARIC CONDITIONS

1. Cabin pressure/Altitude: The 3303 system experienced drifting values when connected to the simulator and when connected to human subjects using the reusable finger probe at altitudes of 7,000 ft and higher. Discussions with the manufacturer indicated that changing the averaging settings should help the problem. Following the instructions in the Clinician's Operation Manual the averaging was increased from the default value of 8 to a new value of 16 for the SpO₂ and pulse averaging. This stopped the drifting values.

2. Rapid Decompression: The 3303 system operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The in-flight evaluation of the 3303 system was performed on a C-9 and a C-130 aeromedical evacuation mission. Due to its large size, the power supply connector prevented it from being plugged into the normal AC outlets on the C-9. The power supply was plugged into a short extension cord which was then plugged into the C-9 AC outlet. Other operations were normal.

SUMMARY

Aeromedical Research found the BCI 3303 to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on battery power. The unit should be used strictly as a trend indication device. The following recommendations and operational restrictions accompany the airworthiness approval of the 3303 system.

a. **The AC power supplies for the BCI 3303 and 3304 are NOT INTERCHANGEABLE.** The power plugs on the pulse oximeter are the same, but the AC power supplies are not. Be sure you have the right AC power supply for the unit. Destruction of the 3303 or the power supply will result from use of the improper supply.

b. When used in-flight to monitor a patient the 3303 should be operated only on battery power.

c. The power supply may be used in-flight to charge the battery, but not while monitoring the patient.

d. The unit readout values may drift up and down at altitudes above 6,500 ft. Correcting this drift may involve changing the averaging factors for SpO₂ and pulse. This drift may be corrected by following the instructions in the operations manual.

e. The 3303 failed parts of the EMI emissions and susceptibility testing. These failures will not endanger the patient or aircraft. The failures should be noted but they are not considered serious enough to ban the use of the 3303.

REFERENCES

1. Mil-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
2. Mil-STD 810E, Environmental Test Methods and Engineering Guidelines.
3. Mil-STD 1472, Human Engineering Design Criteria for Military Systems.
4. Emergency Care Research Institute (ECRI).
5. BCI International, 3303 System, Operator's Manuals.
6. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.
7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.
8. AFI 41-203, Electrical Shock Hazards.
9. AFI 41-201, Equipment Management in Hospitals.

APPENDIX

MANUFACTURER'S SPECIFICATIONS OF THE BCI INTERNATIONAL 3303 SYSTEM

SPECIFICATIONS

General

Size	84 mm wide x 184 mm high x 47 mm deep (3.3 in x 7.25 in x 1.85 in)
Weight	539 grams (19 ounces) with battery
Power	Internal rechargeable battery, wall mount AC power supply
Environmental	Temperature: 0 - 40°C (Operating) -40 - 75°C (Storage) Humidity: 15 - 95 %, noncondensing (Operating) 10 - 90%, noncondensing

DISPLAYS, INDICATORS, & KEYS

SpO ₂	3-digit LED display, 10.9 mm (0.43 in) high
Pulse Rate	3-digit LED display, 9.5 mm (0.375 in) high
Pulse Strength	Logarithmically scaled 8-segment LED bar graph
PROBE	Probe alert indicator
BATT	Low battery indicator
Silenced	Alarm and alert tone silenced indicator
Keys	Nine control keys provided
Brightness	Adjustable brightness of SpO ₂ , pulse rate, and bar graph displays

INDICATORS

POWER Indicates oximeter connected to AC power

CHARGING Indicates oximeter battery is charging

SpO₂

Range 0 - 100%

Accuracy +/- 2% at 70 - 100%
+/- 3% at 50 - 69%

Alarm Limits High 100 - 50% and off in 1% steps
Low 50 - 99% and off in 1% steps

Averaging 4, 8, or 16 pulse beat average

PULSE RATE

Range 30 - 254 BPM

Accuracy +/-2% at 30 - 254 BPM

Averaging 8 or 16 second average

ALARM INDICATORS

Two-tone audible alarm with user-adjustable volume and two-minute or indefinite alarm silence. Corresponding numeric display flashes

PROBE ALERT INDICATOR

Single-tone audible alarm with same volume and silence as alarm tone

PRINTER OUTPUT

SpO₂ and pulse rate can be printed every five (5) seconds (data log). Data saved every thirty (30) seconds can be printed (trend).

BATTERY

Type	Internal rechargeable; not user replaceable
Charge time	Fully charges in about 4 hours
Use Time	Approximately 12 hours continuous use. A new battery will have 14 hours
Indicators	BATT indicator lights when about 30 minutes of battery use remains

AC CHARGER

Wall Mount Style	Input of 105 - 125 VAC, 60 Hz
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